

### REMARKS

Applicants now respond to the Final Office Action of February 21, 2003. Applicants thank the Examiner for the courtesies extended in the telephone conference of February 13, 2003. Applicants file this Amendment After Final to address the questions raised in the telephone conference and the rejections presented in the Final Office Action. Because the amendments made in this paper are merely amendments of form, they are fully supported by the specification, raise no issues of new matter, and do not change the scope of the claims.

#### Specification

The Examiner objected to claims 18 and 69 because they depended from claim 1, cancelled February 11, 2002. (Action at page 2). Applicants note that the Amendment filed November 22, 2002, introduced a typographical error in the dependency of claim 18. Claim 18 as originally filed depended from claim 13, but November 22<sup>nd</sup> Amendment recited it as depending from claim 1. In this paper, claim 18 has been amended to correct this error. This correction also addresses the objection to claim 69 because claim 69 depends from claim 18.

#### Claim Rejections - 35 U.S.C. § 112

The Examiner rejected claims 13 and 70-205 under 35 U.S.C. 112, second paragraph, as being indefinite (Action at page 2). Specifically, the Examiner first rejected claims 204 and 205 for the recitation of "based on blood sampling at half hourly intervals for the first two hours and thereafter at hourly intervals (at the start of a light meal and after an overnight fast)." Solely to facilitate prosecution and without prejudice or disclaimer, claims 204 and 205 have been amended to remove the phrase "(at the start of a light meal and after an overnight fast)."

The Examiner also rejected claims 13, 72-77, 97-102, 109-130, 195-196, 199, and 201-203 as indefinite (Action at pages 2-3) in reciting both "amoxicillin free acid equivalent" and "amoxicillin." Solely to facilitate prosecution and without prejudice or disclaimer, claims 13, 71-77, 97-102, 109-130, 195-196, 199, and 201-203 have been amended to remove the phrase "amoxicillin free acid equivalent." Similarly, claims 13 and 71 have been amended to remove the phrase "organic acid equivalent," and claims 97-102 have been amended to remove the phrase "clavulanic acid equivalent." Support for these amendments can be found in the specification, for example, at page 8, lines 32-36 (noting that the weights of amoxicillin and clavulanate refer to the corresponding free acid unless otherwise indicated and that the weights are to be further adjusted, in accord with conventional practice, page 14, lines 27-30 (ratio of

amoxicillin in the first and second release phases); page 15, lines 20-34 (ratio of amoxicillin to potassium clavulanate); and page 18, lines 29-34 (ratio of amoxicillin to organic acid).

For the foregoing reasons, the claims satisfy the requirements of the second paragraph of Section 112, and Applicants respectfully request withdrawal of the rejection.

Other Amendments to the Claims and New Claims

In reviewing the claims, Applicants noted minor typographical errors. Specifically, Applicants have amended claims 83-85 to correctly list the group of pharmaceutically acceptable organic acids recited in the specification at page 19, lines 18-21. Also, Applicants have amended claims 170-172 to correct a grammatical error in the omission of the word "the," and have amended claims 170-172 to recite to "the second release phase" to enhance the consistency between the claims. In addition, claim 194 now recited a "pharmaceutically acceptable soluble salt of" amoxicillin and "at least one pharmaceutically acceptable" organic acid and the second "release" phase to enhance consistency between claim 194 and claim 13 from which it depends.

This amendment also adds new dependent claims to respiratory tract infections and the particular infections of the respiratory tract, which are also supported by, for example, page 8, lines 14-19. This amendment adds new dependent claims to the treatment regimen of 7 to 14 days, which claims are supported by the specification at, for example, page 8, line 25. Thus, these added claims are fully supported by the specification. Various additional claims (such as claims 179 to 193) have been amended to clarify that the resulting pK profiles, Cmax, AUC etc. are after administration of the composition to the patient. No new matter is believed added.

Applicants submitted herewith a Transmittal with a request to charge our deposit account for the extra claims fees.

Conclusion

With the entry of this Amendment, claims 13, 18, and 69-218 will be pending.

Applicants respectfully request entry of these amendments and the prompt issuance of a Notice of Allowance.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this

paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case, the Commissioner is hereby authorized to charge Deposit Account 19-2570 accordingly.

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Respectfully submitted,



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